EXHIBIT 26

DEPARTMENT OF HEALTH & HUMAN SERVICES — Office of Inspector General

Memorandum

Date MAR 14 2002

From Janet Rehnquist
Inspector General

Subject Medicaid Pharmacy - Actual Acquisition Cost of Generic Prescription Drug Products (A-06-01-00053)

To Thomas Scully
Administrator
Centers for Medicare & Medicaid Services

As a follow-up to our previous work, attached is the Department of Health and Human Services, Office of Inspector General's final report entitled, "Medicaid Pharmacy – Actual Acquisition Cost of Generic Prescription Drug Products." This report provides the results of our review of pharmacy acquisition costs for generic drugs reimbursed under the Medicaid prescription drug program. Most States use average wholesale price (AWP) minus a percentage discount, which varies by State, as a basis for reimbursing pharmacies for drug prescriptions. Although this discount averaged 10.31 percent nationally in 1999, we believe that it is not a sufficient discount to ensure that a reasonable price is paid for drugs. We believe that there is a critical need for States to better control the costs of their Medicaid drug programs because expenditures are rising at a dramatic rate.

Medicaid drug expenditures increased by slightly over 90 percent since our previous review in 1994. In Calendar Year (CY) 1994, expenditures for Medicaid drugs totaled $9.4 billion. Total expenditures for these drugs increased to $17.9 billion by CY 1999. Such increases have adversely affected States' budgets as well as significantly impacted the Federal Government. In our opinion, States could better control costs if they would develop reimbursement methodologies that were more in line with actual drug costs. Therefore, the objective of this review was to develop an estimate of the discount below AWP at which pharmacies purchase generic drugs. Estimates were also developed for the discount below AWP at which pharmacies purchase brand name drugs and those results were summarized in a separate report[1] issued in final to the Centers for Medicare & Medicaid Services (CMS) on August 10, 2001.

As a result of responses to letters sent to selected pharmacies, we obtained pricing information from 217 pharmacies in 8 States and obtained 8,728 invoice prices for generic drug products. The eight States, selected in a stratified random sample, included Colorado, Florida, Indiana, Montana, Texas, Washington, West Virginia, and Wisconsin. We estimated that, nationally, actual drug acquisition cost was an average of 65.93 percent

[1] "Medicaid Pharmacy – Actual Acquisition Cost of Brand Name Prescription Drug Products" (A-06-00-00023)

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below AWP. Our previous estimate, based on CY 1994 pricing data, showed a discount of 42.45 percent below AWP for generic drugs. Therefore, this review showed an increase of over 55 percent in the average discount below AWP for generic drugs from 1994 to 1999.

Our current estimate combined the results for four categories of pharmacies including rural-chain, rural-independent, urban-chain, and urban-independent. We excluded the results obtained from non-traditional pharmacies (nursing home pharmacies, hospital pharmacies, home IV, etc.) because we believed that such pharmacies were able to purchase drugs at substantially greater discounts than a retail pharmacy and including those discounts would inflate our estimate. Unlike brand name drugs, where reimbursement is predominately based on a discounted AWP, reimbursement of generic drugs can be limited by Federal upper limit amounts that are established by CMS.

Based on our review, we determined that there is a significant difference between pharmacy acquisition cost for generic drugs and AWP. We also estimated that changing reimbursement policy consistent with the findings of our report could have saved the Medicaid program as much as $470 million for the 200 generic drugs with the greatest amount of Medicaid reimbursement for CY 1999. We recognize that these calculations do not incorporate all the complexities of pharmacy reimbursement and that acquisition cost is just one factor in pharmacy reimbursement policy. However, we also believe that the results of this report are significant enough to warrant a review of pharmacy reimbursement policy. Per Federal Medicaid regulations, States are required to reimburse pharmacies' ingredient drug portion of the reimbursement based on estimated acquisition cost. Accordingly, we recommended that CMS require the States to bring pharmacy reimbursement for generic drugs more in line with the actual acquisition cost that we identified as being 65.93 percent below AWP.

The CMS responded to our draft report in a memorandum dated March 7, 2002. The CMS concurred that an accurate estimate of the acquisition cost should be used to determine drug reimbursement. The CMS also stated that it will strongly encourage States to reevaluate their reimbursement methodology for drugs, and will continue to encourage States to look for an alternate basis for reimbursement. The CMS plans to share our final report with the States, strongly encourage States to review their estimates of acquisition costs, and follow-up to ensure that their actions take our findings into account.

The CMS also noted that President Bush's Fiscal Year 2003 budget proposes to change the basis for calculating rebates. The change would substitute AWP in place of the average manufacturer's price in the rebate formula. We support the proposed change and agree with CMS' belief that connecting the rebate amount to AWP would result in more accurate AWPs. We previously issued a report[2] to CMS that recommended such a change and detailed the several advantages of doing so.

[2] "Need to Establish Connection Between the Calculation of Medicaid Drug Rebates and Reimbursement for Medicaid Drugs" (A-06-97-00052)

Additionally, we would like to alert you to the pending issuance of another report on the actual acquisition cost of Medicaid prescription drugs. The report will include additional analyses of the data used in this report and the previously issued report on brand name drugs. We have performed the additional analyses in response to interest from our sample States and the pharmacy industry.

We would appreciate your views and information on the status of any action taken or contemplated on the recommendations within the next 60 days. Please refer to Common Identification Number A-06-01-00053 in all correspondence relating to this report.

If you have any questions, please call me or have your staff contact George M. Reeb, Assistant Inspector General for Health Care Financing Audits, at (410) 786-7104.

Attachment

Department of Health and Human Services

OFFICE OF INSPECTOR GENERAL

MEDICAID PHARMACY - ACTUAL ACQUISITION COST OF GENERIC PRESCRIPTION DRUG PRODUCTS

JANET REHNQUIST
INSPECTOR GENERAL

MARCH 2002
A-06-01-00053

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EXECUTIVE SUMMARY

As a follow-up to our previous work, the Office of Inspector General conducted a nationwide review of pharmacy acquisition costs for generic drugs reimbursed under the Medicaid prescription drug program. Since most States use average wholesale price (AWP) minus a percentage discount, which varies by State, as a basis for reimbursing pharmacies for drug prescriptions, the objective of this review was to develop an estimate of the discount below AWP at which pharmacies purchase generic drugs. We also developed estimates for the discount below AWP at which pharmacies purchase brand name drugs and those results were summarized in a separate report.[1]

To accomplish the objective, we selected a stratified random sample of 8 States from a universe of 48 States and the District of Columbia. Arizona was excluded from the universe of States because the Medicaid drug program is a demonstration project using prepaid capitation financing. Tennessee was excluded because of a waiver received to implement a managed care program for Medicaid. Of the 8 States, 2 States (Montana and Florida) were selected from the universe of 10 States and the District of Columbia that were included in our previous review. The other 6 States (Colorado, Indiana, Texas, Washington, West Virginia, and Wisconsin) were selected from the remaining 38 States.

In addition, a random sample of Medicaid provider pharmacies from each State was selected. The pharmacies were selected from each of five categories--rural-chain, rural-independent, urban-chain, urban-independent, and non-traditional (nursing home pharmacies, hospital pharmacies, home IV, etc.). We sampled the non-traditional category separately in order to exclude those pharmacies from our estimates. We believed that such pharmacies were able to purchase drugs at substantially greater discounts than a retail pharmacy and including those discounts would inflate our estimate.

We obtained pricing information from 217 pharmacies in 8 States, which resulted in an analysis of 8,728 invoice prices for generic drug products. We compared each invoice drug price to AWP for that drug and calculated the percentage, if any, by which the invoice price was discounted below AWP. These differences were then projected to the universe of pharmacies in each category for each State and to an overall estimate for each State. Additionally, the results from each State were projected to estimate the nationwide difference between invoice price and AWP for each category.

We estimated that the actual generic drug acquisition cost was a national average of 65.93 percent below AWP. Our previous estimate, based on Calendar Year (CY) 1994 pricing data, showed a discount of 42.45 percent below AWP for generic drugs. As a result, this review showed an increase of 55.31 percent in the average discount below AWP for generic drugs from 1994 to 1999.

This estimate combined the results for four categories of pharmacies including rural-chain, rural-independent, urban-chain, and urban-independent and excluded the results obtained from non-

[1] "Medicaid Pharmacy - Actual Acquisition Cost of Brand Name Prescription Drug Products" (A-06-00-00023)

traditional pharmacies. Unlike brand name drugs for which reimbursement is based predominately on a discounted AWP, reimbursement for generic drugs can be limited by Federal upper limit amounts. Taking the discounts below AWP, as well as those generic drugs for which upper limits could be applied, we calculated that as much as $470 million could have been saved for the 200 generic drugs with the greatest amount of Medicaid reimbursements in CY 1999, if reimbursement had been based on the discount percentages below AWP as identified in this report.

Accordingly, we recommended that the Centers for Medicare & Medicaid Services (CMS) require the States to bring pharmacy reimbursement more in line with the actual acquisition cost of generic drug products, which we identified as being 65.93 percent below AWP.

The CMS Administrator responded to our draft report in a memorandum dated March 7, 2002. The CMS concurred that an accurate estimate of the acquisition cost should be used to determine drug reimbursement. The CMS also stated that it will strongly encourage States to reevaluate their reimbursement methodology for drugs, and will continue to encourage States to look for an alternate basis for reimbursement. The CMS plans to share our final report with the States, strongly encourage States to review their estimates of acquisition costs, and follow-up to ensure that their actions take our findings into account. The full text of CMS' comments is included as **APPENDIX 3**.

INTRODUCTION

BACKGROUND

Medicaid regulations provide for the reimbursement of drugs using two methods. If a drug is a multiple source (generic) drug, then reimbursement is based on the lower of the pharmacist's usual and customary charge to the general public or an upper limit amount plus a dispensing fee. The Federal upper limit amounts are established by the Centers for Medicare & Medicaid Services (CMS). If a drug is a single source (brand name) drug, or a generic drug for which an upper limit amount has not been established, then the reimbursement is the lower of the pharmacist's usual and customary charge to the general public or the estimated acquisition cost (EAC) plus a reasonable dispensing fee. The State agencies are responsible for determining the EAC and the dispensing fee.

The EAC for most States is calculated by using the average wholesale price (AWP) for a drug less a percentage discount. The AWP is the price assigned to the drug by its manufacturer and is compiled by the **Red Book, First DataBank,** and **Medi-Span** for use by the pharmaceutical community. Prior to 1984, most States used 100 percent of AWP for reimbursement of acquisition costs. However, the Office of Inspector General (OIG) issued a report in 1984, which stated that, on average, pharmacies purchased drugs for 15.9 percent below AWP. In 1989, OIG issued a follow-up report that found that pharmacies were purchasing drugs at discounts of 15.5 percent below AWP. Both the 1984 and 1989 reports combined brand name and generic drugs in calculating the percentage discounts and included a comparison of 3,469 and 4,723 purchases, respectively.

In 1989, CMS issued a revision to the State Medicaid Manual (Manual) which pointed out that a preponderance of evidence demonstrated that AWP overstated prices that pharmacies actually paid for drugs by as much as 10 to 20 percent. The Manual issuance further provided that, absent valid documentation to the contrary, it would not be acceptable for a State to make reimbursements using AWP without a significant discount.

In 1997, OIG issued separate reports on the actual acquisition cost of brand name and generic drugs. The 1997 reports were based on comparisons of 18,973 invoice prices for brand name products and 9,075 invoice prices for generic products. The report showed average discounts of 18.30 percent below AWP and 42.45 percent below AWP, respectively. Medicaid drug program expenditures in Calendar Year (CY) 1994 totaled about $9.4 billion. In CY 1999, nationwide drug expenditures for the program increased to about $17.9 billion.

SCOPE

Our review was performed in accordance with generally accepted government auditing standards. The objective of our review was to develop an estimate of the difference between the actual invoice prices of generic prescription drugs to Medicaid pharmacy providers and AWP. Our objective did not require that we identify or review any internal control systems. Our review was limited to ingredient acquisition costs and did not address other areas such as: the effect of Medicaid business as a contribution to other store sales; the cost to provide professional services other than dispensing a prescription for instances such as therapeutic intervention, patient education, and physician consultation; and the cost of dispensing which includes costs for computers, multi-part labels, containers, technical staff, transaction fees, Medicaid-specific administrative costs, and general overhead.

To accomplish our objective, we designed a multistage sampling procedure (a detailed description of our sample design is included as **APPENDIX 1** to this report). State Medicaid agencies were designated as the primary units and Medicaid pharmacy providers as the secondary units. We selected a stratified random sample of 8 States from a universe of 48 States and the District of Columbia. Arizona was excluded from the universe of States because the Medicaid drug program was a demonstration project using prepaid capitation financing. Tennessee was excluded because of a waiver received to implement a managed care program for Medicaid. Of the 8 States, 2 States (Montana and Florida) were selected from a universe of 10 States and the District of Columbia that were included in our previous review. The other 6 States (Colorado, Indiana, Texas, Washington, West Virginia, and Wisconsin) were selected from the remaining 38 States.

We obtained a listing of all Medicaid pharmacy providers from each sample State. The State agencies were responsible for classifying each pharmacy as a chain, independent, or non-traditional. For purposes of this review, a chain was defined as four or more pharmacies with common ownership. We determined whether each pharmacy was rural or urban by comparing the county location for each pharmacy to a 1999 listing of the metropolitan statistical areas and their components. We selected a stratified random sample of 40 pharmacies from each State with 8 pharmacies selected from each of 5 strata--rural-chain, rural-independent, urban-chain, urban-independent, and non-traditional (nursing home pharmacies, hospital pharmacies, home IV, etc.). We sampled the non-traditional category separately so those pharmacies could be excluded from our estimates. We excluded the nontraditional category because we believed that such pharmacies were able to purchase drugs at substantially greater discounts than a retail pharmacy and including those discounts would inflate our estimate.

We requested, from each pharmacy selected, the largest invoice from each different source of supply for a specified month in CY 1999. Supply sources included wholesalers, chain warehouse distribution centers, generic distributors, and manufacturers. Each pharmacy was initially assigned a month from January 1999 through December 1999 in order to provide a cross-section

of this 12-month time period. However, we permitted some pharmacies to provide invoices from other months in 1999, if invoices were not available for the requested period.

We reviewed every line item on the invoices supplied by the sample pharmacies to ensure that invoices contained the information necessary for our review. We eliminated over-the-counter items. Some invoices did not include National Drug Codes (NDC), which were needed to obtain AWP for the drug. We used the **2000 Red Book**, a nationally recognized reference for drug product and pricing information, to obtain NDCs or identify over-the-counter items. Two prominent wholesalers, as well as four chain stores, whose invoices contained the wholesaler item numbers rather than NDCs, provided us with listings that converted their item numbers to NDCs. If we were unable to identify the NDC for a drug, we eliminated the drug.

To verify the drug name, we utilized the drug product file on the CMS web site. In addition to verifying the drug name, we were also able to determine the drug-type indicator from this file. The drug-type indicator showed whether the drug was a brand name or generic drug. We considered single source and innovator multiple source drugs as brand name drugs. Non-innovator drugs were classified as generic drugs. We also obtained from CMS a listing of the top 200 generic drugs in terms of the amount reimbursed by Medicaid for CY 1999.

In order to obtain the AWP for each drug, we obtained a pricing file supplied by **FirstData Bank** through the State of Florida. We compared the invoice drug price to AWP for each drug and calculated the percentage, if any, by which the invoice price was discounted below AWP. If a drug from an invoice was not on the pricing file, we eliminated that drug.

Since some States also use wholesalers acquisition cost (WAC) in their reimbursement methodology, we also compared the invoice drug price to WAC for each drug for which WAC was available on the pricing file. We calculated the percentage, if any, by which WAC must be increased to equate the invoice price. The results of the WAC comparisons are discussed in the **OTHER MATTERS** section of this report and are displayed separately in **APPENDIX 2.**

We used Office of Audit Services (OAS) statistical software to calculate all estimates, as well as to generate all random numbers. We obtained the total number of pharmacies in the universe from the National Council for Prescription Drug Programs. We did not independently verify any information obtained from third-party sources. Additionally, we did not attempt to identify any special discounts, rebates, or other types of special incentives not reflected on the invoices. Our review was conducted by our Little Rock, Arkansas OAS field office, with assistance from our staff from the Office of Counsel to the Inspector General, from July 2000 through June 2001.

FINDINGS

We estimated that the invoice price for generic drugs was a national average of 65.93 percent below AWP. The estimate combined all pharmacy categories except non-traditional pharmacies

and was based on the comparison to AWP of 8,728 invoice prices received from 217 pharmacies in the 8-State sample. The standard error for this estimate was 0.907 percent.[1]

The estimates that invoice prices for generic drugs were discounted below AWP are summarized in the following chart. This chart also shows the number of pharmacies sampled and the number of prices reviewed by individual categories of generic drugs.

Category	Percent Below AWP (Point Estimate 1999)	Sampled Pharmacies	Prices Compared
Rural-Chain	64.39	52	2,073
Rural-Independent	66.64	55	1,142
Urban-Chain	66.97	56	4,491
Urban-Independent	63.70	54	1,022
Non-Traditional	67.07	58	1,185
Overall (Exc. Non-Trad.)	65.93	217	8,728

While the estimate of the discount below AWP of invoice price for generic drugs was significant, this difference is mitigated by Federal upper limit amounts for generic drugs. Reimbursement of the ingredient cost, or EAC, of generic drugs is limited to the upper limit amounts established by CMS. The upper limit amounts are based on 150 percent of AWP for the lowest priced generic equivalent. However, every generic drug does not have an upper limit established and in those cases, reimbursement of EAC is the same as reimbursement of EAC for brand name drugs. The EAC for brand name drugs was not based on AWP in every State or in every situation, however, EAC was predominantly based on a discounted AWP. The average discount below AWP for reimbursement of EAC was 10.31 percent in 1999. Therefore, reimbursement of generic drugs that do not have upper limits is greatly in excess of the actual cost of the drug.

In order to assess the significance of the difference between what Medicaid reimbursed for the ingredient cost of generic drugs and our estimate of what pharmacies actually paid, we calculated the difference for the 200 generic drugs with the most Medicaid reimbursement in CY 1999. For 96 drugs with upper limit amounts, we multiplied Medicaid utilization by the difference between the upper limit (what Medicaid pays for EAC) and AWP discounted by 65.93 percent (pharmacy cost per our review). For 104 drugs without upper limits, we multiplied Medicaid utilization by AWP discounted by the difference between 65.93 percent and the average EAC, AWP minus 10.31 percent. We used the AWP for each drug that was in effect January 1, 1999. We also used the upper limit that was in effect January 1, 1999. There were five drugs that were removed from

[1]The lower limit and upper limit at the 90 percent confidence level were 64.44 and 67.42, respectively.

the upper limits list during the second quarter of the year. For those five drugs, we calculated the first half of the year using the upper limit for EAC and the second half using AWP minus 10.31 percent.

The difference between what Medicaid reimbursed for ingredient cost and our estimate of the amount pharmacies actually paid could be as much as $470 million for CY 1999. The majority, $364 million, of the difference was attributable to the 104 drugs without upper limits established. Reimbursement for 72 of the 96 drugs with upper limits was $115 million more than the estimated cost, while reimbursement for the remaining 24 drugs was $9 million less than the estimated cost. The following table details the results of our calculations:

	Number of Drugs	Difference Between Reimbursement and Acquisition Cost *	Total Reimbursement by Medicaid *
Drugs without upper limits	104	$363,759	$571,891
Drugs with upper limits greater than cost	72	$114,978	$318,321
Drugs with upper limits less than cost	24	$(8,621)	$96,793
Totals	200	$470,116	$987,005

* Amounts in thousands

In addition to the difference between Medicaid reimbursement for generic drugs and our estimate of pharmacy acquisition cost being significant, the estimate of the discount below AWP has also increased substantially since our last review. The results of our last review, which were based on 1994 pricing data, showed that the discount below AWP was 42.45 percent while the results of this review show that the discount below AWP had increased to 65.93 percent, an increase of 55.31 percent since the last review. The following chart provides a comparison of the results of this review and the results of the prior review.

Category	Percent Below AWP (Point Estimate 1994)	Percent Below AWP (Point Estimate 1999)	Percentage Increase
Rural-Chain	47.51	64.39	35.53%
Rural-Independent	47.38	66.64	40.65%
Urban-Chain	37.61	66.97	78.06%
Urban-Independent	46.72	63.70	36.34%
Non-Traditional	57.70	67.07	16.24%
Overall (Exc. Non-Trad.)	42.45	65.93	55.31%

CONCLUSIONS AND RECOMMENDATIONS

Based on our review, we have determined that there is a significant difference between pharmacy acquisition cost for generic drugs and AWP. We have also estimated that changing reimbursement policy consistent with the findings of our report could have resulted in savings of as much as $470 million for the 200 most reimbursed generic drugs in CY 1999. We recognize that these calculations do not incorporate all the complexities of pharmacy reimbursement and that acquisition cost is just one factor in pharmacy reimbursement policy. However, we also believe that the results of this report are significant enough to warrant a review of pharmacy reimbursement policy. Per Federal Medicaid regulations, States are required to reimburse pharmacies' ingredient drug portion of the reimbursement based on EAC. Therefore, we recommended that CMS require the States to bring pharmacy reimbursement for generic drugs more in line with the actual acquisition cost that we identified as being 65.93 percent below AWP.

CMS' COMMENTS AND OIG'S RESPONSE

The CMS Administrator responded to our draft report in a memorandum dated March 7, 2002. The CMS concurred that an accurate estimate of the acquisition cost should be used to determine drug reimbursement. The CMS also stated that it will strongly encourage States to reevaluate their reimbursement methodology for drugs, and will continue to encourage States to look for an alternate basis for reimbursement. The CMS plans to share our final report with the States, strongly encourage States to review their estimates of acquisition costs, and follow-up to ensure that their actions take our findings into account.

In addition, CMS expressed concern that our report showed Medicaid reimbursement for 24 drugs with Federal upper limits was below cost (page 5 of report). However, after discussions

with OIG staff, CMS found that our findings resulted from applying an average discount to individual drug prices, and that if applying each drug's individual discount, the Federal upper limit prices were not below actual cost. The full text of CMS' comments is included as **APPENDIX 3**.

The CMS also noted that President's fiscal year 2003 budget proposes to change the basis for calculating rebates. The change would substitute AWP in place of the average manufacturer's price in the rebate formula. We support the proposed change and agree with CMS' belief that connecting the rebate amount to AWP would result in more accurate AWPs. We previously issued a report[2] to CMS that recommended such a change and detailed the several advantages of doing so.

OTHER MATTERS

For the eight States that we reviewed, in addition to our comparison of AWP to acquisition cost, we also compared WAC to invoice price. This was done because some States use WAC plus a percentage in determining their pharmacy reimbursement methodology. We estimated that the invoice price for generic drugs was a national average of 30.55 percent below WAC rather than it being higher and therefore, perhaps supporting that a percentage be added to WAC. Our estimate combined all pharmacy categories except non-traditional pharmacies and was based on the comparison to AWP of 6,370 invoice prices received from 217 pharmacies in the 8-State sample. The standard error for this estimate was 1.30 percent. The results of our review show that WAC was not a true wholesale acquisition price and was significantly higher than the actual acquisition costs for generic drugs. Therefore, we believe the use of WAC plus a percentage as the basis for reimbursing pharmacies could result in payments which significantly exceed the actual acquisition cost of generic drugs. The detailed results of the WAC comparisons are shown in **APPENDIX 2**.

[2] "Need to Establish Connection Between the Calculation of Medicaid Drug Rebates and Reimbursement for Medicaid Drugs" (A-06-97-00052)

SAMPLE DESCRIPTION

Sample Objectives:

Develop a nationwide estimate of the extent of the discount below AWP of actual invoice prices paid to Medicaid pharmacies for generic drugs.

Population:

The primary sampling population was all States providing coverage of prescription drugs as an optional service under section 1905 (a) (12) of the Social Security Act (the Act). Section 1903 (a) of the Act provides for Federal financial participation in State expenditures for prescription drugs.

Sampling Frame:

The primary sampling frame was a listing of all States participating in the Medicaid prescription drug program except for Arizona and Tennessee. Arizona was excluded because the Medicaid drug program is a demonstration project using prepaid capitation financing and Tennessee was excluded because of a waiver received to implement a managed care program for Medicaid.

Sample Design:

A stratified multistage sample was designed with States as the primary sample units and Medicaid pharmacy providers within those States as the secondary sample units. A stratified random sample of States was selected for the primary sample and a stratified random sample of pharmacies was selected for the secondary sample. A sample of eight pharmacies was selected from each of five strata. The five strata of pharmacies were rural-chain, rural-independent, urban-chain, urban-independent, and non-traditional (nursing home pharmacies, hospital pharmacies, home IV, etc.). Each pharmacy was assigned a month from 1999 for which to provide invoices. All pharmacies were initially assigned a month from January 1999 through December 1999 in a method designed to provide a cross-section of the 12-month period. However, some pharmacies were permitted to submit invoices from other months in 1999, as invoices were not available for the month originally assigned. The largest invoice from each of four different sources of supply was requested. The sources of supply were identified as wholesalers, chain warehouse distribution centers, generic distributors, and direct manufacturer purchases. All invoice prices were compared to AWP.

Sample Size:

Eight States were selected for review from our primary sampling frame. Eight pharmacies were selected from each stratum of our secondary sample frame. Therefore, a maximum of 40 pharmacies was selected from each State. Of the 8 States, 2 States were selected from the universe of 10 sampled States plus the District of Columbia in our previous review. The remaining 6 States were selected from the remaining universe of 38 States.

Source of Random Numbers:

OAS statistical sampling software was used to generate the random numbers.

Characteristics to be Measured:

From our review of the pharmacy invoices, we calculated the percentage of the discount below AWP of actual invoice prices for all drugs on the invoices submitted.

Treatment of Missing Sample Items:

No spare was substituted for a pharmacy that refused to provide the requested information. If a stratum had eight or fewer pharmacies, we reviewed all pharmacies in that stratum. Spares were substituted for pharmacies that were not providers during the review period and for misclassified pharmacies. If a pharmacy did not send an invoice for a particular type of supplier, we assumed that the pharmacy did not purchase drugs from that supplier type during the assigned month.

Estimation Methodology:

We used OAS statistical software for stratified multistage variable sampling to project the percentage difference between actual invoice prices and AWP for each stratum, as well as an overall percent difference.

Other Evidence:

We obtained AWP from a pricing file received from the State of Florida.

APPENDIX 2

NATIONWIDE SAMPLE RESULTS
GENERIC DRUGS

AWP Statistics

	Category	Sample's Universe of Pharmacies	Sample Pharmacies (Sample Size)	Data Points	Percent Below AWP (Point Estimate)
A	Rural-Chain	1,008	52	2,073	64.39
W	Rural-Independent	1,243	55	1,142	66.64
P	Urban-Chain	5,745	56	4,491	66.97
	Urban-Independent	2,398	54	1,022	63.70
	Non-Traditional	1,123	58	1,185	67.07
	Overall (Excl. Non-Trad.)	10,394	217	8,728	65.93

WAC Statistics

	Category	Sample's Universe of Pharmacies	Sample Pharmacies (Sample Size)	Data Points	Percent Below WAC (Point Estimate)
W	Rural-Chain	1,008	52	1,569	-27.13
A	Rural-Independent	1,243	55	856	-27.01
C	Urban-Chain	5,745	56	3,193	-33.04
	Urban-Independent	2,398	54	752	-27.80
	Non-Traditional	1,123	56	893	-35.97
	Overall (Excl. Non-Trad.)	10,394	217	6,370	-30.55

APPENDIX 3

DEPARTMENT OF HEALTH & HUMAN SERVICES

Centers for Medicare & Medicaid Services

Administrator
Washington, DC 20201

DATE: MAR 7 2002

TO: Janet Rehnquist
Inspector General

FROM: Thomas A. Scully
Administrator

SUBJECT: Office of Inspector General (OIG) Draft Report: *Medicaid Pharmacy – Actual Acquisition Cost of Generic Prescription Drug Products* (A-06-01-00053)

Thank you for the opportunity to review and comment on the above-referenced draft report regarding the results of OIG's review of pharmacy acquisition costs for the top 200 generic drugs reimbursed under the Medicaid prescription drug program. The OIG report disclosed a significant difference between the pharmacy acquisition cost for generic drugs and the average wholesale price (AWP); i.e., the pharmacy acquisition cost was 65.93 percent below AWP. Please note that in President Bush's proposed fiscal year (FY) 2003 budget, the Administration proposes to change the basis for calculating the rebates to reduce the price that Medicaid pays for drugs, which we believe will have a substantial impact on the price Medicaid pays for all drugs.

Due to the manipulation of AWPs, many state Medicaid agencies overpay for Medicaid drugs. To this end, the President's FY 2003 budget proposes to change the basis for calculating the drug manufacturers Medicaid rebates from the difference between the manufacturer's best price and the average manufacturer's price to the difference between the manufacturer's best price and AWP. While this provision in the President's budget is targeted for brand-name drugs, where the rebate is based on best price, we believe that by connecting the rebate amount to AWP, all manufacturers will be pressured to report more accurate pricing data to the compendia drug manufacturers' Medicaid rebates that publish AWP. We also note that as we develop the legislative proposal for the provision, we may also address generic drugs in rebasing the rebate.

We also have a technical comment regarding your analysis of drugs with Federal upper limit (FUL) amounts. In assessing what Medicaid paid for generic drugs, the OIG report included 96 drugs with FUL amounts. The report showed that for 72 of the 96 drugs, payment was above cost- while the remaining 24 drugs showed a reimbursement below cost. The Centers for Medicare & Medicaid Services (CMS) was concerned that this assessment did not accurately capture the Medicaid reimbursement for those 24 drugs and followed up with the OIG to further understand the OIG methodology.

During the course of that discussion, we discovered that the OIG had applied an average discount of 65.93 percent to the 24 drugs, rather than applying each drug's individual discount. When these amounts were then compared to the corresponding FUL prices, it resulted in an overstatement in the number of drugs with FUL prices less than cost. When the OIG went back and identified each drug's individual discount from the AWP, it found that most were substantially greater than the AWP minus the 65.93 percent discount that had been applied and that the FUL prices were not below actual cost. We realize that the OIG audit did not take into consideration the calculations used in the FUL program and that the OIG findings resulted from applying an average discount to individual drug prices. However, in looking at individual drug prices and using the compendia data provided to CMS, we believe that the FUL amounts accurately reflect what the pharmacy pays for the drugs.

We appreciate the effort that went into this report and the opportunity to review and comment on the issues it raises. Our specific comments on the OIG recommendation follow.

OIG Recommendation

The CMS should require the states to bring pharmacy reimbursement for generic drugs more in line with the actual acquisition cost of generic drug products, which the OIG identified as being 65.93 percent below AWP.

CMS Response

We are very concerned with the OIG's findings in this report and believe follow-up action with the states is warranted. We concur that an accurate estimate of the acquisition cost should be used to determine drug reimbursement. We previously noted the shortcomings of using AWP as a basis for reimbursement and will strongly encourage states to reevaluate their reimbursement methodology for drugs. In addition, we will continue to encourage states to look for an alternate basis for reimbursement. Once this report is finalized, we plan to share it with the states, strongly encourage them to review their estimates of acquisition costs, and follow up with them to ensure that their actions take these findings into account.